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**PATENT**

Atty. Docket No.  
**AR02164USACON1**

CN 27777

Date: Feb. 10, 2004 By: Lois E. Miller

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): David E. EDGREN et al.

Serial No.: 10/696,370

Filed: October 28, 2003

For: ANTIDEPRESSANT DOSAGE  
FORM

Group Art Unit: to be assigned

Examiner: to be assigned

**INFORMATION DISCLOSURE  
STATEMENT**

Honorable Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the

mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).

☒ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:

☒ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

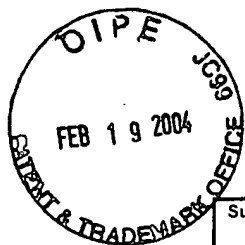
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Respectfully submitted,

  
Attorney for Applicants

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PTO-SB-08A (08-00)

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 3

|                        |                  |
|------------------------|------------------|
| Application Number     | 10/696,370       |
| Filing Date            | October 28, 2003 |
| First Named Inventor   | David E. EDGREN  |
| Group Art Unit         | Not yet assigned |
| Examiner Name          | Not yet assigned |
| Attorney Docket Number | AR02164USACON1   |

**U.S. PATENT DOCUMENTS**

| Examiner<br>Initials | Cite<br>No. <sup>1</sup> | U.S. Patent Document |                                      | Name of Patentee or Applicant<br>of Cited Document | Date of Publication<br>of Cited Document<br>mm-dd-yyyy | Pages, Columns, Lines,<br>where relevant passages<br>or relevant figures appear |
|----------------------|--------------------------|----------------------|--------------------------------------|--|--|---|
|                      |                          | Number               | Kind Code <sup>2</sup><br>(if known) |  |  |   |
|                      | AA                       | 2,799,241            |                                      | Wurster  | 07/16/1957   |   |
|                      | AB                       | 3,133,132            |                                      | Loeb et al.  | 05/12/1964   |   |
|                      | AC                       | 3,173,876            |                                      | Zobrist  | 03/16/1965   |   |
|                      | AD                       | 3,276,586            |                                      | Rosaen   | 10/04/1966   |   |
|                      | AE                       | 3,541,005            |                                      | Strathmann et al.                                  | 11/17/1970   |   |
|                      | AF                       | 3,541,006            |                                      | Bixler et al.                                      | 11/17/1970   |   |
|                      | AG                       | 3,546,142            |                                      | Michaels et al.                                    | 12/08/1970   |   |
|                      | AH                       | 3,589,122            |                                      | Zaffaroni  | 08/10/1971   |   |
|                      | AI                       | 3,589,123            |                                      | Zaffaroni  | 08/10/1971   |   |
|                      | AJ                       | 3,845,770            |                                      | Theeuwes et al.                                    | 11/05/1974   |   |
|                      | AK                       | 3,916,899            |                                      | Theeuwes et al.                                    | 11/04/1975   |   |
|                      | AL                       | 4,063,064            |                                      | Saunders et al.                                    | 12/13/1977   |   |
|                      | AM                       | 4,088,864            |                                      | Theeuwes et al.                                    | 05/09/1978   |   |
|                      | AN                       | 4,111,201            |                                      | Theeuwes et al.                                    | 09/05/1978   |   |
|                      | AO                       | 4,160,020            |                                      | Ayer et al.  | 07/03/1979   |   |
|                      | AP                       | 4,200,098            |                                      | Ayer et al.  | 04/29/1980   |   |
|                      | AQ                       | 4,285,987            |                                      | Ayer et al.  | 08/25/1981   |   |
|                      | AR                       | 4,327,725            |                                      | Cortese et al.                                     | 05/04/1982   |   |
|                      | AS                       | 4,535,189            |                                      | Husbands et al.                                    | 08/13/1985   |   |
|                      | AT                       | 4,611,078            |                                      | Husbands et al.                                    | 09/09/1986   |   |
|                      | AU                       | 4,612,008            |                                      | Wong et al.  | 09/16/1986   |   |
|                      | AV                       | 4,761,501            |                                      | Husbands et al.                                    | 08/02/1988   |   |

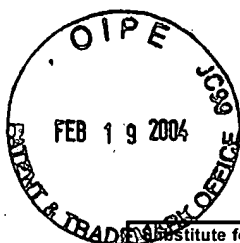
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| Examiner<br>Signature |  | Date<br>Considered |  |
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<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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STATEMENT BY APPLICANT**

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Sheet 2 of 3

|                        |                  |
|------------------------|------------------|
| Application Number     | 10/696,370       |
| Filing Date            | October 28, 2003 |
| First Named Inventor   | David E. EDGREN  |
| Group Art Unit         | Not yet assigned |
| Examiner Name          | Not yet assigned |
| Attorney Docket Number | AR02164USACON1   |

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|----------------------|--------------------------|----------------------|--------------------------------------|--|--|---|
|                      |                          | Number               | Kind Code <sup>2</sup><br>(if known) |  |  |   |
|                      | AW                       | 4,765,989            |                                      | Wong et al.  | 08/23/1988   |   |
|                      | AX                       | 4,783,337            |                                      | Wong et al.  | 11/08/1988   |   |
|                      | AY                       | 4,842,867            |                                      | Ayer et al.  | 06/27/1989   |   |
|                      | AZ                       | 4,863,744            |                                      | Urquhart et al.                                    | 09/05/1989   |   |
|                      | BA                       | 4,946,687            |                                      | Ayer et al.  | 08/07/1990   |   |
|                      | BB                       | 4,948,592            |                                      | Ayer et al.  | 08/14/1990   |   |
|                      | BC                       | 4,950,486            |                                      | Ayer et al.  | 08/21/1990   |   |
|                      | BD                       | 4,966,769            |                                      | Guittard et al.                                    | 10/30/1990   |   |
|                      | BE                       | 5,190,765            |                                      | Jao et al.   | 03/02/1993   |   |
|                      | BF                       | 6,440,457            | B1                                   | Edgren et al.                                      | 08/27/2002   |   |

**FOREIGN PATENT DOCUMENTS**

| Examiner<br>Initials | Cite<br>No. <sup>1</sup> | Foreign Patent Document |                     |                        | Name of Patentee or<br>Applicant of Cited Document | Date of Publication<br>of Cited Document<br>mm-dd-yyyy | Pages, Columns, Lines,<br>where relevant<br>passages or relevant<br>figures appear | T <sup>6</sup> |
|----------------------|--------------------------|-------------------------|---------------------|------------------------|--|--|--|----------------|
|                      |                          | Office <sup>3</sup>     | Number <sup>4</sup> | Kind Code <sup>5</sup> |  |  |  |                |
|                      | BG                       | EP                      | 0 112 669           | A2                     | American Home Products                             | 07/04/1984   |  |                |
|                      |                          |                         |                     |                        |  |  |  |                |
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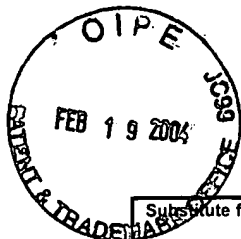
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| First Named Inventor   | David E. EDGREN  |
| Group Art Unit         | Not yet assigned |
| Examiner Name          | Not yet assigned |
| Attorney Docket Number | AR02164USACON1   |

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

| Examiner's Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published | T <sup>2</sup> |
|----------------------|-----------------------|--|----------------|
|                      | BH                    | Louis F. Fabre & H. Paul Putman, "An ascending single-dose tolerance study of WY-45,030, A bicyclic antidepressant, in healthy men," <u>Current Therapeutic Research</u> , 42(5):901-909, November 1987.   |                |
|                      | BI                    | Alvin Felmeister, "Powders," <u>Remington's Pharmaceutical Sciences</u> , 14 <sup>th</sup> Edition, Ch 86 & 87, pp. 1626-1648, Mack Publishing Co., 1970.  |                |
|                      | BJ                    | Goodman & Gilman, <u>The Pharmacological Basis of Therapeutics</u> , 4 <sup>th</sup> Ed., Page 182, Macmillan Publishing Co., New York, 1970.  |                |
|                      | BK                    | Goodman & Gilman, <u>The Pharmacological Basis of Therapeutics</u> , 7 <sup>th</sup> Ed., Page 7, Macmillan Publishing Co., New York, 1985.  |                |
|                      | BL                    | Goodman & Gilman, <u>The Pharmacological Basis of Therapeutics</u> , 8 <sup>th</sup> Ed., Pages 407 & 411, Pergamon Press, New York, 1990.   |                |
|                      | BM                    | P. Grafton, "General principles for designing with plastics," <u>Modern Plastics Encyclopedia</u> , 46:62-71, 1969.  |                |
|                      | BN                    | Robert E. King, "Tablets, Capsules, and Pills," <u>Remington's Pharmaceutical Sciences</u> , 14 <sup>th</sup> Edition, Ch. 87, pp. 1649-1680, Mack Publishing Co., 1970.   |                |
|                      | BO                    | Mark A. Longer & Joseph R. Robinson, "Sustained-Release Drug Delivery Systems," <u>Remington's Pharmaceutical Sciences</u> , 18 <sup>th</sup> Edition, Ch 91, pp. 1676-1686, Mack Publishing Co., 1990.  |                |
|                      | BP                    | <u>The Merck Index</u> , 11 Ed., page 1365 & MISC-107, 1989. "Sodium Nitrate"  |                |
|                      | BQ                    | <u>The Merck Index Online</u> , Merck & Co. 1996, 1997. "10079 Monograph Name: Venlafaxine"  |                |
|                      | BR                    | Scott & Roff, <u>Handbook of Common Polymers</u> , CRC Press., Cleveland Ohio, 1971.   |                |
|                      | BS                    | Dale E. Wurster, "Air-Suspension Technique of Coating Drug Particles", <u>J. Am. Pharm. Assoc.</u> , 48(8):451-454, August 1959  |                |
|                      | BT                    | Dale E. Wurster, "Preparation of Compressed Tablet Granulations by the Air-Suspension Technique II", <u>J. Am. Pharm. Assoc.</u> , 49(2):82-84, February 1960.   |                |

|                    |  |                 |  |
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| Examiner Signature |  | Date Considered |  |
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1 Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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